

## **REMARKS**

### ***Status of the Claims***

Claims 1-10 are pending in this application. Claims 1 and 4 are currently amended; claim 10 is canceled; and claim 11 is added.

Claim 1 has been amended to recite that a method of measuring the amount of "25-hydroxy vitamin D metabolite, 1 $\alpha$ ,25-dihydroxy vitamin D metabolite or both" in a sample. Support for this amendment is found on page 32, line 20 to page 33, line 37.

Claims 1 and 4 have been amended for improved grammar and to better comply with formal requirements.

Claims 1 and 4 have been amended to recite that the functional group, "A," is selected from the group consisting of biotin, digoxigenin, amino acids, characteristic amino acids and peptide sequences, FITC, proteins, peptide groups, protein-A, protein G and vitamin D derivatives. Support for this amendment is found, for instance, at page 6, lines 2-12.

New claim 11 depends from claim 1, and recites that the competitive binding assay is an enzyme immunoassay, an enzyme-linked immunosorbent assay, a radio immunoassay, an immunoradiometric assay, a luminescence assay, a fluorescence immunoassay or an immunofluorometric assay. Support for this claim is found, for instance, at page 9, line 24 to page 10, line 6.

### **1. Claim Rejections under 35 USC §112, Second Paragraph**

The Examiner has rejected claims 1-10 as allegedly indefinite. (Office Action, pages 2-4). Applicants respectfully traverse.

The Examiner has imposed a series of indefiniteness rejections in paragraphs 4-6 and 8-9 on pages 2-4 of the Office Action. Applicants have amended the claims as described above, thereby obviating the rejections.

In regard to the indefiniteness rejection of paragraph 7, page 3, the Examiner contends that it is unclear whether the method recited in claim 1 is useful to detect vitamin D metabolites 25-hydroxy vitamin D and 1 $\alpha$ ,25-dihydroxy vitamin D when both are in the sample. Here, Applicants submit that it is clear that the detection method recited in claim 1 is capable of detecting 25-hydroxy vitamin D and 1 $\alpha$ ,25-dihydroxy vitamin D when they are alone or together in a sample. Applicants direct the Examiner's attention to pages 32-33 of the Specification, where it is disclosed that the ratio of 25-hydroxy vitamin D to 1 $\alpha$ ,25-dihydroxy vitamin D in many samples is 1000:1, and both 25-hydroxy vitamin D and 1 $\alpha$ ,25-dihydroxy vitamin D are detected in such samples.

In order to specifically measure the amount of 1 $\alpha$ ,25-dihydroxy vitamin D in a sample in which the 25-hydroxy vitamin D to 1 $\alpha$ ,25-dihydroxy vitamin D ratio is 1000:1, chromatographic separation steps are performed to isolate 1 $\alpha$ ,25-dihydroxy vitamin D in a sample, which is then measured individually. (Page 33, lines 17-37). Applicants have amended claim 1 to better describe this situation. Accordingly, Applicants submit that this aspect of claim 1 is clear, and respectfully request reconsideration and withdrawal of the rejection.

## **2. Claim Rejections under 35 USC §102**

The Examiner has rejected claims 1-8 and 10 as allegedly anticipated by Holick et al. (WO 97/24127). (Office Action, pages 4-6). Applicants respectfully traverse.

Applicants have amended claim 1 to incorporate the limitation formerly recited in claim 10 regarding the detected 25-hydroxy vitamin D and 1 $\alpha$ ,25-dihydroxy vitamin D metabolites having a displacement efficiency of 1. Applicants submit that, because Holick et al. are silent as to this

feature of the invention. Accordingly, Holick et al. is not an anticipating reference against the present claims, and Applicants respectfully request reconsideration and withdrawal of the rejection.

### **3. Claim Rejections under 35 USC §103**

The Examiner has rejected claim 9 as allegedly obvious over Holick et al. in view of DeLuca et al. (USPN 5,064,770). (Office Action, page 6). Applicants respectfully traverse.

As discussed above, Holick et al. fails to teach the presently claimed method for detecting 25-hydroxy vitamin D and 1 $\alpha$ ,25-dihydroxy vitamin D metabolites having a displacement efficiency of 1. The Examiner relies on DeLuca et al for its teaching of magnetic particles for anchoring binding molecules to the particle. But this teaching by DeLuca does not rescue the deficiency in Holick et al.; so even the combination of Holick et al. and DeLuca et al. fails to teach the instantly claimed detection methods. The Examiner has therefore failed to establish a *prima facie* case of obviousness, and Applicants respectfully request reconsideration and withdrawal of this rejection.

### **4. Conclusion**

In view of the above amendment, Applicants believes the pending application is in condition for allowance. The favorable action of withdrawal of the standing rejections and issuance of a Notice of Allowance are respectfully requested.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee is attached hereto.

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Should there be any matter precluding allowance of the application that can be addressed by a telephone conversation, the Examiner is invited to call the undersigned at the number listed below to discuss the matter.

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Respectfully submitted,

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